PACKAGE INSERT

SCHEDULING STATUS: S2
PROPRIETARY NAME (AND DOSAGE FORM):

DOXY CO (TABLETS)

COMPOSITION:

Each tablet contains:	Paracetamol	450 mg
	Doxylamine Succinate	5 mg
	Caffeine	30 mg
	Codeine Phosphate	10 mg

PHARMACOLOGICAL CLASSIFICATION:
A 2.8 Analgesic combinations.
PHARMACOLOGICAL ACTION:
DOXY CO has analgesic, antipyretic and antihistaminic properties.
INDICATIONS:
For mild to moderate pain associated with tension.
CONTRA-INDICATIONS:
Hypersensitivity to any of the active or other ingredients. Severe liver function impairment. Acute intermittent porphyria. Contra-indicated in respiratory depression, especially in the presence of cyanosis and excessive bronchial secretion, after operation on the biliary tract, acute alcoholism, head injuries and conditions in which intracranial pressure is raised. It should not be given during an attack of bronchial asthma or in heart failure secondary to chronic lung disease. Contra-indicated in patients taking monoamine oxidase inhibitors or within 14 days of stopping such treatment.
WARNINGS:
The dosage in renal functional impairment must be reduced.
Should be taken with caution by asthmatics.
This medicine may lead to drowsiness and-impaired concentration, which may be aggravated by simultaneous intake of alcohol, or other central nervous system depressant agents. Patients should be warned against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration may lead to accidents.
Dosage in excess of those recommended may cause severe liver damage. Consult a doctor if no relief is obtained from the recommended dosage. Use with caution in renal disease.
Exceeding the prescribed dose, together with prolonged and continuous use of this medication may lead to dependency and addiction.
Do not use continuously for longer than 10 days without consulting your doctor.
In the event of over dosage or suspected overdose and not withstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately.
INTERACTIONS
The depressant effects of codeine are enhanced by depressants of the central nervous system such as alcohol, anaesthetics, hypnotics sedatives and phenothiazines.
The effects of atropine and tricyclic antidepressants may be enhanced by doxylamine succinate. Doxylamine succinate may enhance the sedative effects of central nervous system depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquillisers.
PREGNANCY AND LACTATION
Safety has not been established in pregnancy and lactation.
DOSAGE AND DIRECTIONS FOR USE:
Adults and Children over 12 years: Two tablets every four hours as needed. Do not exceed 8 tablets per day.
DO NOT EXCEED THE RECOMMENDED DOSE.
DO NOT USE FOR LONGER THAN TEN (10) DAYS WITHOUT CONSULTING YOUR DOCTOR. EXCESSIVE USE OF THIS MEDICINE MAY BE DANGEROUS.
SIDE-EFFECTS AND SPECIAL PRECAUTIONS:
Paracetamol:
Sensitivity reactions resulting in reversible skin rashes or blood disorders may occur. This rash is usually erythromatous or urticarial, but sometimes more serious and may be accompanied by drug fever and mucosal lesions. Pancreatitis may occur.
The use of paracetamol has been associated with the occurrence of thrombocytopenia, neutropenia, pancytopenia and leucopenia agranulocytosis.
Patients suffering from kidney or liver disease should take paracetamol under medical supervision.
Codeine Phosphate
Codeine may cause nausea, vomiting, constipation, drowsiness, confusion, dry mouth, sweating, facial flushing, vertigo, respiratory depression, bradycardia, palpitation, hypotension, orthostatic hypotension, circulatory failure, hyperthermia, restlessness, deepening coma, euphoria, changes of mood and miosis, muscle rigidity, pruritus, urticaria and sweating. Micturition may be difficult and there may be ureteric or biliary spasms and a diuretic effect. Raised intracranial pressure may occur.
Codeine should be given with caution to patients with hypothyroidism, adrenocortical insufficiency, impaired kidney or liver function, myasthenia gravis, prostatic hypertrophy or shock. It should be used with caution in patients with inflammatory or obstructive bowel disorders. The dosage should be reduced in elderly and debilitated patients. Prolonged use of high doses of codeine has produced dependence.
Caffeine
Side-effects of caffeine include nausea, headache and insomnia. Large doses may cause restlessness, excitement, muscle tremor, tinnitus, scintillating scotoma, tachycardia and extrasystole. Caffeine increases gastric secretion and may cause gastric ulceration.
Caffeine should be given with care to patients with a history of peptic ulceration. With prolonged use some degree of tolerance and psychic dependence may occur.
Give with caution to patients with hyperthyroidism, cardiac arhythmias or other cardiovascular disease, or epilepsy as these conditions may be exacerbated.
Doxylamine Succinate
A common side-effect of doxylamine succinate is sedation (see **"WARNINGS").** Other side-effects include gastro-intestinal disturbances, headache, blurred vision, tinnitus, elation or depression, irritability, nightmares, anorexia, difficulty in micturition, dryness of the mouth, tightness of the chest and tingling, heaviness and weakness of the hands, nausea, vomiting, diarrhoea and parasthesia.
Symptoms of paradoxical central nervous system include insomnia, nervousness, tachycardia, hypotension, tremors, muscle twitching and convulsions.
Hypersensitivity reactions such as skin rashes, urticaria, purpura, angioedema, bronchospasm or anuria may occur. Large doses may precipitate fits in epileptics. Allergy and anaphylaxis may occur. Erythema multiforme and exfoliative or bullous dermatitis may occur. Symptoms of porphyria may be exacerbated.
Blood dyscrasias, including agranulocytosis, eosinophilia, leucopenia, thrombocytopenia and haemolytical anaemia may occur. Doxylamine succinate has anticholinergic properties and should be used with care in conditions such as glaucoma and prostatic hypertrophy. Doxylamine succinate may mask the symptoms of damage caused by ototoxic medicine and may affect metabolism of medicine in the liver.
KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
See **"SIDE EFFECTS AND SPECIAL PRE-CAUTIONS"**
Antihistamines (Doxylamine Succinate)
Overdosage of doxylamine succinate causes sedation. Overdosage may be fatal, especially in infants and children in whom the main symptoms are central nervous stimulation and antimuscarinic effects, including ataxia, excitement, hallucinations, muscle tremor, convulsions, dilated pupils, dry mouth, flushed face and hyperpyrexia. Deepening coma, cardiorespiratory collapse **and death may** occur within 18 hours. In adults the usual symptoms are central nervous depression with drowsiness, coma and convulsions. Hypotension may also occur. Treatment of antihistamine overdose is symptomatic and supportive.
Paracetamol
Prompt treatment is essential. In the event of an over dosage, consult a doctor immediately, or take the person to a hospital directly. A delay in starting treatment may mean the antidote is given too late to be effective. Evidence of liver damage is often delayed until after the time for effective treatment has lapsed. Susceptibility to Paracetamol toxicity is increased in patients who have taken repeated high doses (greater than 5 -10 g/day) of Paracetamol for several days, in chronic alcoholism, chronic liver disease, AIDS, malnutrition, and with the use of drugs that induce liver microsomal oxidation such as barbiturates, Isoniazid, Rifampicin, Phenytoin and Carbamazepine. Symptoms of Paracetamol over dosage in the first 24 hours include pallor, nausea, vomiting, anorexia and possibly abdominal pain. Mild symptoms during the first two days of acute poisoning do not reflect the potential seriousness of the over dosage. Liver damage may become apparent 12 to 48 hours, or later after ingestion, initially by elevation of the serum transaminase and lactic dehydrogenase activity, increased serum bilirubin concentration and prolongation of the prothrombin time. Liver damage may lead to encephalopathy, coma and death. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Abnormalities of glucose metabolism and metabolic acidosis may occur. Cardiac arrhythmias have been reported.
Treatment for Paracetamol over dosage:
Although evidence is limited it is recommended that any adult person who has ingested 5 - 10 grams or more of Paracetamol (or a child who has had more than 140 mg/kg) within the preceding four hours, should have the stomach emptied by lavage (emesis may be adequate for children) and a single dose of 50 g activated charcoal given via the lavage tube. Ingestion of amounts of Paracetamol smaller than this may require treatment in patients susceptible to Paracetamol poisoning (see above). In patients who are stuperose or comatose endotracheal intubation should precede gastric lavage in order to avoid aspiration.
N-acetylcysteine should be administered to all cases of suspected overdose as soon as possible preferably within eight hours of over dosage, although treatment up to 36 hours after ingestion may still be of benefit, especially if more than 150 mg/kg of Paracetamol was taken.
IV: IV: An initial dose of 150 mg/kg in 200 ml glucose injection, given intravenously over 15 minutes, followed by an intravenous infusion of 50 mg/kg in 500 ml of glucose injection over the next 4 hours, and then 100 mg/kg in 1 000 ml over the next 16 hours. The volume of intravenous fluids should be modified for children.
ORAL: Although the oral formulation is not the treatment of choice, 140 mg/kg dissolved in water may be administered initially, followed by a 70 mg/kg solution every 4 hours for 17 doses.
Plasma Paracetamol levels should be determined four hours after ingestion in all cases of suspected over dosage. Levels done before four hours, unless high, may be misleading. Patients at risk of liver damage, and hence requiring continued treatment with N-acetylcysteine, can be identified according to their plasma Paracetamol level. The plasma Paracetamol level can be plotted against time since ingestion in the normogram below.
Those, whose plasma Paracetamol levels are above the "normal treatment line", should continue N-acetylcysteine treatment with 100 mg/kg IV over sixteen hours repeatedly until recovery. Patients with increased susceptibility to liver damage as identified above, should continue treatment if concentrations are above the "high risk treatment line". Prothrombin index correlates best with survival. Monitor all patients with significant ingestions for at least ninety-six hours.
Codeine Phosphate
Poisoning with codeine produces central stimulation with exhilaration and in children, convulsions, followed by vomiting, drowsiness, respiratory depression and cyanosis and coma. Treatment is symptomatic and supportive.
IDENTIFICATION: A yellow flat tablet, scored on one side.
PRESENTATION:
Securitainers of 20, 100 and 500 tablets.
Blister packs of 10, 18, 20, 54 and 100 tablets.
STORAGE INSTRUCTIONS:
Store below 25°C in a dry place. Keep well closed.
KEEP OUT OF REACH FROM CHILDREN.
REGISTRATION NUMBER: 33/2.8/0098
NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Gulf Drug Company (Pty) Ltd
22 Burnside Drive
Old Mill Industrial Park
Mount Edgecombe, 4300
www.gulfdrug.co.za
DATE OF PUBLICATION OF THIS PACKAGE INSERT: 20 September 2002
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REGISTRATION NUMBER: 33/2.8/0098
NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
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DATE OF PUBLICATION OF THIS PACKAGE INSERT: 20 September 2002
P/330098/2
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